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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL DELK and AUGUSTUS FELIX

Appeal 2009-0306
Application 09/481,120
Technology Center 3700

Decided:¹ March 26, 2009

Before DONALD E. ADAMS, ERIC GRIMES, and RICHARD M.
LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The two-month time period for filing an appeal or commencing a civil action, as provided for in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is a decision on appeal from the final rejection of claims 12-16 under 35 U.S.C. § 103(a). Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claimed invention is to a surgical irrigator that comprises a pump, a handpiece with tubing connected at one end of the pump, and a lubricant coated spike at the other end of the pump. Claims 12-16 are pending and stand rejected under 35 U.S.C. § 103(a) as obvious in view of the Kullas et al. (US 6,436,072 B1, Aug. 20, 2002) and Dennehey et al. (US 4,201,406, May 6, 1980) patents (Ans. 3).

Appellants group claim 12-16 together (App. Br. 3). We select independent claim 12 as representative of the claims. Claim 12 reads as follows:

12. A surgical irrigator, comprising a pumping unit having an inlet and an outlet, a handpiece and tubing connecting the outlet of said pumping unit to said handpiece, said pumping unit including a support for the pumping unit, a flexible tube connecting at one end to said inlet, and a spike connected to the other end of said flexible tube for connecting said inlet to an irrigation bag, said spike being adapted to penetrate a fitting in said irrigation bag and coated with a lubricant.

ISSUE

The Examiner relies on Kullas for its teaching of a surgical irrigator and Dennehey for its teaching of a lubricated spike. The issue in this appeal is whether the Examiner erred in finding that an ordinary skilled artisan would have had reason to utilize Dennehey's lubricated spike in Kullas's surgical irrigator.

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). “Often, it will be necessary . . . to look to interrelated teachings of multiple [references] . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, ___, 127 S. Ct. 1727, 1740-41 (2007). “[T]his analysis should be made explicit”, *id.* at ___, 127 S. Ct. at 1741, and it “can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at ___, 127 S. Ct. at 1739. “[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at ___, 127 S. Ct. at 1740.

Although § 103 does not define what is meant by “prior art,” this determination is frequently couched in terms of whether the art is analogous or not, i.e., whether the art is “too remote to be treated as prior art.” *In re Sovish*, 769 F.2d 738, 741 . . . (Fed.Cir.1985).

. . . .

Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of

endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 . . . (Fed.Cir.1986); *In re Wood*, 599 F.2d 1032, 1036 . . . (CCPA 1979).

In re Clay, 966 F.2d 656, 658-59 (Fed. Cir. 1992).

FINDINGS OF FACT

Claim 12

1. Claim 12 is directed to a surgical irrigator comprising a pump, a pump inlet connected by tubing to a handpiece, and a pump outlet connected to a flexible tube with a spike. The spike is for attaching the pumping unit to an irrigation bag. As explained in the Specification, the irrigation bag comprises a liquid which is pumped through the handpiece into a surgical site as directed by a surgeon (Spec. 1-3).
2. The spike is “adapted to penetrate a fitting in said irrigation bag and coated with a lubricant.”

Scope and content of the prior art

In making an obviousness determination, we must first ascertain the scope and content of the prior art. *Graham*, 383 U.S. at 17. The following numbered findings of fact (“FF”) summarize the prior art relied upon by the Examiner in setting forth the basis of the rejection (Ans. 3-4):

The Kullas patent

3. Kullas describes a medical irrigation pump and pump system (Kullas, Abstract).
4. Appellants do not dispute the Examiner’s findings that Kullas shows the claimed combination of a pumping unit, handpiece, and flexible tube with a

spike for connecting the pump to an irrigation bag (Ans. 3; App. Br. 3; Finding of Fact (“FF”) FF1).

The Dennehey patent

5. Dennehey describes “a spike connector of the type that is used to connect a tubing set to a medical solution container” (Dennehey, at col. 1, ll. 5-7).

Dennehey states that its spike connector is “applicable . . . to various types of medical procedures” (*id.* at col. 2, ll. 45-50).

6. The spike is surrounded by a tube spaced apart from the spike’s external wall which minimizes bacterial contamination caused by accidental touching of the spike (Dennehey, at col. 1, ll. 54-56; col. 2, ll. 4-10 and 60-68; Figure 1 shows spike 28 and tube 34).

7. “Spike 28 is preferably formed of a material having a relatively slippery surface so that the spike can be inserted easily into port 12 [of the solution bag]. Lubricating material may be applied to the spike and may comprise silicone or other lubricating materials as are well-known in the art” (Dennehey, at col. 3, ll. 14-20).

8. “In the illustrative embodiment [of Dennehey], tube 34 has an internal diameter that is suited for enabling the tube to be coupled to port 12 with a snug pressure fit” (Dennehey, at col. 3, ll. 26-28).

Difference between the prior art and the claimed invention

Once the scope and content of the prior art has been determined, the next step is to identify the differences between the prior art and the claimed invention. *Graham*, 383 U.S. at 17. The following numbered findings of fact are pertinent to this issue:

9. The difference between Kullas and claim 12 is that Kullas does not describe an inlet spike “coated with a lubricant” as recited in the claim (Ans. 3-4).

Reason to combine the prior art

After ascertaining the differences between the prior art and the claimed invention, the next step is to identify a reason why persons of ordinary skill in the art would have been prompted to combine the prior art to have made the claimed invention. *KSR*, 550 U.S. at ___, 127 S. Ct. at 1741.

10. Citing Dennehey’s disclosure at column 3, lines 5-20 (*see* FF7), the Examiner stated that persons of ordinary skill in the art would have had reason “to modify the spike of Kullas with a lubricant as taught by Dennehey so that the spike can be easily inserted into the irrigation bag” (Ans. 4).

ANALYSIS

It is undisputed all the features recited in claim 12 are described in the Kullas patent, with the exception of the claimed inlet spike “coated with a lubricant” (FF9). The Examiner finds that a lubricated inlet spike had been used in the prior art, as evidenced by Dennehey, to facilitate its insertion into a medical solution bag (FF7). The Examiner reasons that it would have been obvious to the ordinary skilled artisan to have utilized a lubricated spike in Kullas’s irrigation pump assembly for the advantages taught by Dennehey (FF10).

Appellants contend that the Examiner’s reasoning is flawed because it “ignores” key differences between the claimed invention and the prior art. Appellants argue that Dennehey teaches an apparatus for introducing a

medical solution into a patient, not surgical irrigation “directed by a surgeon to a surgical site” as in the claimed invention (App. Br. 5). Appellants state that Dennehey’s purpose is to prevent spike contamination and therefore it utilizes a spike structure which produces “frictional forces . . . substantially higher than would ordinarily be encountered if the spike alone were inserted into [the solution bag] port” (*id.*)

These arguments do not convince us that the Examiner erred. In making an obviousness determination, the first step is to ascertain the prior art. *Graham*, 383 U.S. at 17. Prior art which is pertinent to the claimed invention is referred to as “analogous” prior art. It is well-established that there are two criteria to be applied when determining whether a prior art reference is analogous: (1) whether the reference is from the same field of endeavor as the claimed invention, and (2) if the reference is not within the same field of endeavor, “whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *Clay*, 966 F.2d at 658-59. When neither criterion is met, the reference is deemed “non-analogous” and is not considered pertinent to the § 103 determination.

In this case, Appellants have not provided evidence that Dennehey is within a different field of endeavor from the Kullas patent and claim 12. Nor have Appellants provided evidence that Dennehey’s teachings about medical solution delivery would not have been considered pertinent to the irrigation device as taught in Kullas and claimed by Appellants.

“‘[A]rguments of counsel cannot take the place of evidence lacking in the record.’” *Estee Lauder Inc. v. L’Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997) (quoting *Knorr v. Pearson*, 671 F. 2d 1368, 1373 (Fed. Cir. 1982)). To the contrary, as pointed out by the Examiner, Dennehey expressly states

that its spike connector can be utilized in “various types of medical procedures” (FF5; Ans. 4) and, therefore, absent countervailing evidence, would be viewed as relevant to the Kullas device which is also a medical procedure involving solution delivery. Thus, even if Kullas and Dennehey were considered to be in different fields of endeavor, Dennehey is still reasonably pertinent to the claimed invention because it involves the same kind of problem addressed by Kullas and the instant inventors.

Claim 12 does not exclude the inlet spike from having the spaced apart protector tube described by Dennehey. Therefore, we are not convinced that lubricant would be unnecessary because the frictional forces would be substantially higher than were an ordinary spike to be used (App. Br. 5). The factual findings equally support a reason to have utilized Dennehey’s protected spike with both the surrounding tube and lubricant coating for the advantages described by Dennehey, i.e., to minimize bacterial contamination and achieve a snug fit (FF6-8). A combination of known elements for their established functions “is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at ___. 127 S. Ct. at 1739.

Furthermore, Appellants have not substantiated their argument that a lubricant would be unnecessary in the absence of Dennehey’s protective tube (App. Br. 6). According to Dennehey, a slippery surface facilitates spike entry into the solution bag port (FF7). There is no evidence, merely attorney argument, that this teaching would be understood to be limited to the connector spike described by Dennehey, rather than generally applicable to other spike types.

Appellants contend “irrigators have been known for many years yet prior to appellants’ invention it was not suggested that the spike used to connect the irrigator to the irrigation bag should be lubricated” (App. Br. 5).

It is well-established that “[a]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.” *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004); *accord In re Kahn*, 441 F.3d 977, 990-91 (Fed. Cir. 2006).

CONCLUSION OF LAW

The Examiner did not err in finding that an ordinary skilled artisan would have had reason to utilize Dennehey’s lubricated spike in Kullas’s surgical irrigator. We therefore affirm the rejection of claim 12, and dependent claims 13-16 which were argued with it. *See* 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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